## UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

# **FSIS NOTICE**

36-16

6/1/16

## NOT READY-TO-EAT COMMINUTED POULTRY SAMPLING PROGRAM

DO NOT IMPLEMENT THIS NOTICE UNTIL JULY 1, 2016.

NOTE: Inspection program personnel who collect these samples are allowed 1 hour of official time to read this notice.

## I. PURPOSE

- A. This notice instructs inspection program personnel (IPP) at establishments that produce not ready-to-eat (NRTE) comminuted chicken and turkey products that they are to sample NRTE (raw) comminuted poultry as part of ongoing sampling of comminuted chicken and turkey products. This notice reissues most of the content of FSIS Notice 31-15, *Not Ready-to-Eat Comminuted Poultry Sampling Project*, with the following modifications and clarifications.
  - 1. FSIS will begin assessing whether establishments meet the new performance standards for comminuted poultry sampled collected on and after July 1, 2016. FSIS will continue to use the sampling project codes for comminuted poultry product formerly used in exploratory sampling;
  - 2. IPP are to continue to sample mechanically separated chicken (MSC) and mechanically separated turkey (MST) that is not intended to be processed into RTE product in a domestic official establishment. However, at this time, the performance standards for comminuted chicken and turkey do not apply to MSC or to MST;
  - 3. This notice clarifies that dumpling-type products (wontons, eggrolls, and other comminuted chicken or turkey products wrapped in dough or other similar covering) are <u>not</u> eligible for sampling (see Section V. A.1.);
  - 4. FSIS is clarifying that finished NRTE comminuted poultry product receiving an off-site antimicrobial intervention such as HPP or irradiation are not to be sampled unless the comminuted poultry product is returned to the producing establishment after such intervention is applied (see Section V. I): and
  - 5. This notice clarifies that finished comminuted poultry products are to be collected <u>prior</u> to freezing unless the establishment applies a validated antimicrobial intervention that achieves a reduction in *Salmonella* or *Campylobacter* at or after the freezing step (see Section V. H.).
- B. For the purposes of sampling, "NRTE comminuted poultry product" is any raw non-breaded, non-battered raw poultry product that has been (1) ground, (2) mechanically separated, or (3) hand- or

DISTRIBUTION: Electronic	NOTICE EXPIRES: 7/1/17	OPI: OPPD

mechanically-deboned <u>and</u> further chopped, flaked, minced, or otherwise processed to reduce particle size. This product includes a final (consumer-ready) product or intermediary product for further processing as NRTE product that is destined for sale as NRTE (including raw or heat-treated but not fully cooked) product to consumers. IPP are to sample this product, and FSIS will test it for *Salmonella* and *Campylobacter*.

#### II. BACKGROUND

- A. FSIS finalized and announced the performance standards for comminuted chicken and turkey products and announced them in the *Federal Register* notice "New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule".
- B. The number of samples assigned to be collected at each establishment will vary based on factors including establishment production volume.
- C. When exploratory NRTE comminuted poultry sampling began, FSIS increased the analytic portion for *Salmonella* analysis from 25 grams to 325 grams, consistent with the current *Escherichia coli* O157:H7 analytic sample portions. FSIS has validated the current FSIS *Salmonella* detection method (FSIS Microbiology Laboratory Guidebook Chapter 4) for poultry using 325-gram samples. IPP are to be aware that if establishments choose to analyze their products for *Salmonella*, they are not required to use the same sample analysis procedures as FSIS. However, the Hazard Analysis and Critical Control Points (HACCP) regulations require that the establishment maintain documents that support that its verification activities, and the frequency with which it performs them, are appropriate to accomplish their intended purpose (9 CFR 417.5(a)(3)).
- D. Sampling tasks are assigned based on information in the establishment's Public Health Information System (PHIS) profile.
- E. FSIS will begin assessing whether establishments are meeting the new performance standards for NRTE product collected on and after July 1, 2016. Until the implementation date of this notice (July 1, 2016), IPP are to follow the current instructions.

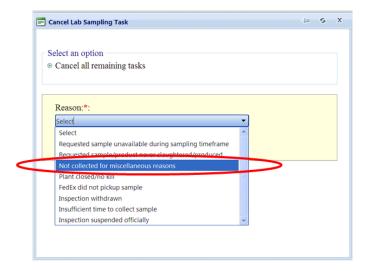
## **III. SCHEDULING AND DOCUMENTING SAMPLES**

- A. IPP will receive sample requests through PHIS. NRTE (raw) comminuted poultry samples will be requested separately for chicken (CH) and turkey (TU) products. Mechanically separated species will be assigned a different sampling code than ground and other comminuted products.
  - 1. IPP in establishments that produce Ground Product or Other Comminuted product, as identified in PHIS, will receive directed sampling tasks through PHIS as "HC\_CH\_COM01" (for chicken) or "HC\_TU\_COM01" (for turkey). IPP are only to sample raw ground or other comminuted products, and not mechanically separated species, under these project codes.
  - 2. IPP in establishments that produce Mechanically Separated Species, as identified in PHIS, will receive directed sampling tasks through PHIS as "EXP\_CH\_MSK01" (for chicken) or "EXP\_TU\_MSK01" (for turkey). IPP are only to sample mechanically separated species, and not other types of raw comminuted chicken or turkey products, under these project codes.
- B. NRTE (raw) comminuted poultry samples will only be requested for an establishment in which the establishment's PHIS profile indicates at least one product group entry with an average daily production volume of greater than 1,000 pounds of one or both of the following:

- 1. Ground Product or Other Comminuted product (HC\_CH\_COM01 or HC\_TU\_COM01 sampling tasks will be assigned).
- 2. Mechanically Separated (Species) (EXP\_TU\_MSK01 or EXP\_CH\_MSK01 sampling tasks will be assigned).
- C. IPP are to notify official establishment management before collecting samples.
- D. Each month, the number of comminuted poultry samples assigned for collection at each establishment will be based on factors such as establishment production volume. Some establishments may not receive any comminuted poultry sampling tasks in a given month. It is possible that there will be a different number of samples assigned to an establishment each month. Establishments will not be assigned a sampling task in PHIS if all of the eligible finished product groups in the PHIS profile have the intended use "For RTE Cooking Only."

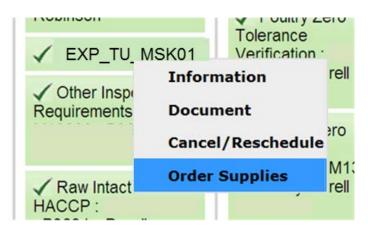
**NOTE:** Products marked with intended use "For RTE Cooking Only" are processed into RTE product at an official establishment. Processing into RTE product is not limited to cooking. It can also be accomplished by drying, high pressure pasteurization (HPP), or some other process, provided that lethality is achieved, and the other criteria described in Chapter VII, Section II, of <u>FSIS Directive 10,250.1</u>, Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products, are met.

- 1. IPP are to collect NRTE (raw) comminuted poultry samples no more frequently than once per week, when possible. In the case that there are more samples than weeks in the sampling window, IPP should schedule sample collection evenly throughout the month, and if necessary more than one sample could be taken in a given week.
- 2. If an establishment is assigned samples for both mechanically separated (EXP\_CH\_MSK01 or EXP\_TU\_MSK01) and ground or other comminuted (HC\_CH\_COM01 or HC\_TU\_COM01) within the same sampling window, then IPP are to collect the appropriate sample for each sampling code as described above in Section III A. For example, it would be acceptable to collect a mechanically separated chicken sample and a ground chicken sample in the same week.
- E. IPP are to document the sample collection as directed in <u>FSIS Directive 13,000.2</u>, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System, a*nd are to ensure that all requested information is entered completely and accurately into PHIS.
- F. If an establishment does not produce eligible product, but IPP are assigned sampling tasks to collect comminuted poultry, IPP are to cancel the NRTE comminuted poultry sampling tasks from both the task list and (if scheduled) the task calendar, using the correct reason.
  - 1. If the establishment produces a product that is eligible for NRTE comminuted poultry sampling but is not producing during the sampling window, then IPP are to select "requested sample unavailable during the sampling timeframe."
  - 2. If the establishment has never produced eligible product, then IPP are to enter "requested sample/product never slaughtered/produced." IPP are to verify that the product is entered correctly in the PHIS profile and make any needed corrections.
- G. If sampling tasks remain in the task list at the end of the sampling window, IPP are to cancel them from the task list and provide the correct reason. When canceling tasks in the task list, IPP are to select "Not collected for miscellaneous reasons" if the reason for cancellation is other than the specific options listed. IPP are NOT to allow sampling tasks to expire.



### IV. SAMPLING SUPPLIES

- A. The FSIS laboratories will automatically send sampling supplies to establishments that will be assigned the sampling tasks to collect ground or other comminuted chicken and turkey products (HC\_CH\_COM01 and HC\_TU\_COM01). When IPP return a sample of ground or other comminuted chicken or turkey product collected under this sampling code, the laboratories will send a replacement box of sampling supplies.
- B. When mechanically separated species (EXP\_CH\_MSK01 or EXP\_TU\_MSK01) sampling tasks are assigned in PHIS, IPP are to request sampling supplies through PHIS. To make this request, IPP are to first schedule a sample on the Task Calendar. Once it is scheduled, IPP right-click the scheduled lab sampling task on the Task Calendar, then select "Order Supplies" from the drop down menu. IPP are to schedule the sample and request sampling supplies at least 72 hours before collecting the scheduled sample.



**NOTE:** The FSIS laboratories will not automatically send out sampling supplies for mechanically separated species (EXP\_CH\_MSK01, or EXP\_TU\_MSK01) sampling tasks before sampling task assignment in PHIS, because of the relatively low number of samples that FSIS anticipates assigning.

C. If sampling supplies for ground or other comminuted chicken and turkey products (HC\_CH\_COM01 and HC\_TU\_COM01) are lost, damaged, or otherwise unavailable for these sampling tasks, IPP are to request them through PHIS, as described in section B above. They are to schedule a sample (HC\_CH\_COM01 and HC\_TU\_COM01) in PHIS, then right click on this task to order supplies at least 72 hours prior to the date of collection.

- D. If two collection events are scheduled close together (for example, on a Friday and the following Monday), IPP are to ensure they have adequate sampling supplies available. If IPP need to request sampling supplies, they are to do so as described in section B above, in time to ensure the samples can be collected.
- E. Should IPP have questions or concerns regarding the sampling supplies, they are to submit them to one of the FSIS laboratories via Outlook by selecting one of the below addressees from the Global Address List.



- F. IPP will receive the M 20 box (shipping container) with sorting labels affixed to the exterior. The shipping container for the HC\_CH\_COM01 and HC\_TU\_COM01 projects will have a white label on the exterior with HC\_CH\_COM01 and HC\_TU\_COM01 in black lettering. The shipping container will contain the following supplies (under Comminuted Poultry Sampling Supplies and Guidance, box 1a; accessible through the "IPP Help" button. IPP will be able to open the "IPP Help" button from the Icon on their FSIS Computer Desktop):
  - 1. 1 Pair sterile gloves;
  - 2. 2 24 oz. lined Whirl-Pak® bags;
  - 3. 1 − 2 gallon re-sealable zipper-lock type containment bag;
  - 4. 1 6" x 12" plastic sleeve (for printed/signed PHIS sample form);
  - 5. Sample seals (Form 7255-2A/2B);
  - 6. 1 − Absorbent pad;
  - 7. Cardboard separator(s);
  - 8. Gel coolant pack(s); and
  - 9. 3 FedEx (preprinted) airbills (1 per FSIS Laboratory for submitting the sample).
- G. When IPP request sampling supplies for mechanically separated species (EXP\_CH\_MSK01, or EXP\_TU\_MSK01), the sampling supplies kit will include the supplies listed in F. above, as well as a sterile scoop, a sterile spatula, and two disinfectant towelettes (see Comminuted Poultry Sampling Supplies and Guidance, box 1b; accessible through the "IPP Help" button). The shipping container for the EXP\_CH\_MSK01 and EXP\_TU\_MSK01 projects will have a white label on the exterior with EXP\_CH\_MSK01 and EXP\_TU\_MSK01 in black lettering.

## V. PRODUCT ELIGIBILITY

- A. HACCP Verification sampling on and after July 1, 2016 (sampling codes HC\_CH\_COM01 and HC\_TU\_COM01) differs from exploratory sampling in the following ways:
- 1. Dumpling-type products (wontons, eggrolls, and other comminuted chicken or turkey products wrapped in dough or other similar covering) are <u>not</u> eligible for sampling.

- 2. IPP are to collect ground or other comminuted poultry products prior to freezing <u>except</u> when an establishment applies a validated antimicrobial intervention that achieves a reduction in *Salmonella* or *Campylobacter* at or after the freezing step. If such a validated intervention is applied during or after freezing, then products are to be sampled after this step. Section V. H. provides instructions related to collecting product that has received an intervention at or after freezing.
- B. IPP are to randomly collect eligible raw comminuted poultry samples by product group. IPP are to ensure that the product collected is accurately identified in the related sampling collection task questionnaire in PHIS (see Questions when collecting "Ground Product" and "Other Comminuted" Products (HC\_CH\_COM01 and HC\_TU\_COM01) for ground and other comminuted product, and Questions when collecting "Mechanically Separated Species" (EXP\_CH\_MSK01 and EXP\_TU\_MSK01) for mechanically separated product). These questions are accessible through the "IPP Help" button.
  - 1. IPP are to collect products in the "Ground Product" and "Other Comminuted" product groups (for example, fresh raw sausage and fresh raw patties) under only the HC\_CH\_COM01 and HC\_TU\_COM01 sampling codes, randomly selecting from available eligible raw ground and other comminuted (but not mechanically separated) products. Comminuted products containing added ingredients such as spices, seasonings, rosemary extract, or vegetables (but not other meat or poultry) are eligible for sampling.
  - 2. IPP are to collect "Mechanically Separated Species" under only the EXP\_CH\_MSK01 and EXP\_TU\_MSK01 sampling codes.
- C. The <u>only</u> products eligible for sampling are those categorized in the PHIS HACCP processing category "Raw Product Non-intact;" finished product category "Raw ground, comminuted, or otherwise non-intact chicken/turkey;" and production volume categories "Ground Product," "Mechanically Separated Product," or "Other Comminuted." Products in any other PHIS HACCP processing categories are <u>not</u> to be sampled under the NRTE (raw) comminuted poultry sampling project.
- D. If an establishment produces raw comminuted product categorized in the PHIS HACCP processing category "Raw Product Non-intact," but the product will undergo further processing into a raw product at another establishment, then the product is eligible for sampling at the producing and the further processing establishments. For example, if an establishment produces ground chicken and moves it to another establishment for further processing into raw chicken patties, then the ground chicken is eligible for sampling at the producing establishment, and the raw chicken patties are eligible for sampling at the further processing establishment.
- E. IPP are to sample product only from a product group with a production volume of <u>greater</u> than 1,000 pounds average daily production. IPP are not to sample product from a product group with a production volume of less than 1,000 pounds average daily production.
- **EXAMPLE**: If an establishment produces ground chicken with an average daily production volume of greater than 1,000 pounds, but produces other raw comminuted chicken products such as raw chicken sausage with an average daily production volume of less than 1,000 pounds, then IPP are to schedule only ground chicken (and not the other raw comminuted products) for collection.
- F. Only raw comminuted poultry products that are not intended for further processing into RTE products at another federally inspected establishment are eligible for sampling. Consistent with current FSIS *Salmonella* sampling procedures for NRTE (raw) product, when an establishment either processes all or moves all such product to another official establishment for further processing into RTE product, IPP are not to collect a sample of such product for the NRTE comminuted poultry sampling project (see Chapter VII, Section II, FSIS Directive 10,250.1.

**NOTE**: Official establishments include only domestic federally-inspected establishments and <u>do not</u> include foreign, State-inspected, or food service establishments, including hotels, restaurants, and institutions (HRI). Therefore, if an establishment moves NRTE (raw) comminuted poultry product to a foreign, State-inspected, or food service establishment for further processing into RTE product, that product is eligible for sampling under the NRTE comminuted poultry sampling project at the producing establishment.

- G. If an establishment produces NRTE (raw) comminuted chicken or turkey product on more than one shift, IPP are to alternate sample collection from a different shift each sampling event so that all shifts are represented during a sampling window.
- H. Finished comminuted poultry products are to be sampled <u>prior</u> to freezing unless the establishment applies a validated antimicrobial intervention that achieves a reduction in (and not only reduces outgrowth of) *Salmonella* or *Campylobacter* on comminuted poultry product at or after freezing. If establishments apply such an antimicrobial intervention at or after freezing, IPP are to collect comminuted product <u>after</u> such interventions have been applied. In this case, IPP are to randomly select comminuted product to be sampled, and the establishment would need to develop a tempering procedure for such product and apply it prior to IPP collecting the sample. The sample collection date entered in PHIS is the date that IPP collect the product, after it has been tempered.
- I. If off-site interventions, such as high pressure pasteurization (HPP) or irradiation, are applied to prevent or control *Salmonella* or *Campylobacter* in comminuted poultry, IPP are to sample such product after they return to the producing establishment after such an off-site intervention is applied.

**NOTE:** At this time, it is not possible to collect product which has received an off-site intervention at the establishment which applied the off-site intervention. FSIS is working to resolve this issue.

J. When answering the "Product name" question in PHIS for each sample, IPP are to provide as much detail as possible. For example, IPP collect a sample of ground turkey thigh made from deboned thigh meat. IPP would correctly indicate the product name as "ground turkey thigh (deboned)." It is not sufficient to respond "thigh trim" or "ground turkey" as the product name for this sample.



- K. The following products are not eligible for sampling under this project:
  - 1. Injected, needle- or blade-tenderized, or vacuum tumbled raw poultry products are <u>not NRTE</u> comminuted poultry. IPP are not to sample such products under the NRTE comminuted poultry sampling project. However, if the injected, needle-tenderized, or vacuum tumbled product is

subsequently processed in the same establishment to reduce particle size, such as by grinding or other process, then the raw comminuted products manufactured from these non-intact source materials would be eligible for sampling. For example, if injected chicken breast trimmings are source materials used in raw ground poultry, then the raw ground poultry itself (but not the trimmings) is eligible for sampling;

- 2. Mixed-species NRTE comminuted poultry products (for example, raw sausage containing both ground turkey and ground pork or containing both ground chicken and turkey);
- 3. Diced, chunked, or sectioned poultry that is not in small pieces or that is otherwise not comminuted. In general, this would refer to pieces 3/4 inch or greater in any dimension;
- 4. Hand- or mechanically-deboned products that are not further chopped, flaked, minced, or otherwise processed to reduce particle size;
- 5. Any comminuted poultry that is battered or breaded;
- 6. Whole muscle parts because they are not comminuted:
- 7. Poultry trimmings because they are not comminuted;
- 8. Comminuted poultry that is portioned (product from a larger package broken down into smaller packages but not cut-up or otherwise processed) only or repackaged only;
- Any NRTE finished product containing comminuted poultry that has been cooked or received a full lethality treatment (for example, in the HACCP processing category "Heat-treated but not Fully Cooked – Not Shelf Stable"); and
- 10. Dumplings, wontons, potstickers, eggrolls, pelmeni, or other comminuted chicken or turkey products wrapped in dough or other similar covering.

#### VI. SAMPLE COLLECTION

A. IPP are to collect finished product in its final package whenever possible. IPP are to collect the appropriate number of packages so that the sample equals two pounds. IPP are to place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies. Finished comminuted poultry products are to be sampled <u>prior</u> to freezing when no validated antimicrobial interventions are at or after the freezing step.

**NOTE**: IPP are not to use the Whirl-pak® bags when collecting product in its final packaging.

- B. For finished product not available in final packaging or when the package is too large, IPP are to collect the sample aseptically after all antimicrobial interventions have been applied and as close to packaging as possible (e.g., grab sample from a combo bin or grab from a 40-pound box) and use the sterile Whirl-Pak® bags as instructed below. Finished comminuted chicken products are to be sampled <u>prior</u> to freezing.
- C. IPP are to use only the sampling and shipping materials provided by the FSIS laboratory specific to the NRTE comminuted poultry sampling project, as identified in Sections IV. F. and IV. G. and shown (under Comminuted Poultry Sampling Supplies and Guidance accessible through the "IPP Help" button), and refer to FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications for complete instructions on the proper use of sample seals. IPP are not to use spoons or other implements to collect a sample other than what is included in FSIS-provided sampling supplies.

- D. When using the Whirl-Pak® bags, IPP are to:
  - 1. Randomly select product to sample.

**NOTE**: Randomization of product selection is critical to achieve sample variety.

- 2. Collect sufficient product to fill the two provided Whirl-Pak® bags up to the fill-line indicated on each bag. When the bag is closed, product should meet the line indicated on the bag ( (under Comminuted Poultry Sampling Supplies and Guidance accessible through the "IPP Help" button) boxes 2- 3). IPP are not to underfill or overfill the bag. The total weight of the two bags of samples should be approximately two pounds.
- 3. Ensure that each Whirl-Pak® bag is properly closed. To do this, IPP must carefully squeeze out the air remaining in the bag and tightly fold over the top at least four times as trapped air and loose closures may lead to leakage. When folding over the tops of each bag, IPP are to ensure that they do not touch the bag near its opening. Next, IPP are to fold over the side tabs to secure the folds in place and to not tie the ends (under Comminuted Poultry Sampling Supplies and Guidance, boxes 4 through 6; accessible through the "IPP Help" button). This process is to be repeated for the second bag; and
- 4. Apply one small barcode label from FSIS Form 7355-2A/2B, Laboratory Sample Container Seal Set, to each Whirl-Pak® bag (see Comminuted Poultry Sampling Supplies and Guidance, box 7; accessible through the "IPP Help" button).
- E. IPP are to place both Whirl-Pak® bags in the same secondary containment bag (zipper-lock type bag), expel excess air from the bag, and close the containment bag using the zipper lock closure.
- F. IPP are to apply the medium sized bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to the secondary containment bag (see Comminuted Poultry Sampling Supplies and Guidance, box 8; accessible through the "IPP Help" button).
- G. IPP are to:
  - 1. Affix one small bar-coded sample label from FSIS Form 7355-2A/2B sample seal set to the completed and signed printed sample form;
  - 2. Affix the bar-coded label in the space provided at the top center of the form; and
  - 3. Place the completed form in the plastic sleeve provided.
- H. IPP are to retrieve the frozen gel coolant packs from the freezer and retrieve the pre-chilled shipping container.
- I. IPP are to place the absorbent pad in the bottom of the container, followed by the gel coolant pack, the cardboard separator, and the sampled product (within the 2-gallon containment bag) (see Comminuted Poultry Sampling Supplies and Guidance, box 9; accessible through the "IPP Help" button).

**NOTE**: When needed, after the sample specimen has been placed in the shipper, IPP are to place a second cardboard separator and then a frozen gel coolant pack in the shipping container to ensure that the sample arrives at the laboratory at an acceptable temperature.

- J. IPP are to place the completed sample form and any unused sample seals in the container.
- K. IPP are to insert the foam plug and press down to minimize the space between the sample and foam

plug. If the shipping container does not have a foam plug, place the insulated lid on the container. Do not overfill the shipping container.

**NOTE**: IPP are not to tape or wrap the samples or use any newspaper or similar material as packing material. Using such materials may result in the sample being discarded by the laboratory.

- L. IPP are to complete the information on the large bar-coded seal from the same FSIS Form 7355-2A/2B sample seal set, sign the seal, and affix the signed, large bar code seal across the seam of the closed sample box flap.
  - 1. For shipping containers with self-sticking closures, apply the seal across the closed inner flap of the box parallel to the edge of the closed flap. Then close the outer flap over the seal; or
  - 2. For shipping containers without self-sticking closures, apply the seal across the closed outer flaps. Fasten the outer flaps with clear packaging tape.
- M. IPP are to review the information on the pre-printed FedEx airbills provided with the sampling supplies and select the airbill that matches the FSIS Laboratory printed on PHIS Form 8000-18. Enter return address information on that airbill.
- N. IPP are to remove any old stamp receipts and carrier shipping bar codes from the container and affix the FedEx airbill addressed to the FSIS laboratory printed on PHIS Form 8000-18 on the shipping container.
- O. IPP are to ensure that the sample remains under FSIS control until pickup by FedEx. IPP are to ensure sample security by following instructions in <u>FSIS Directive 7355.1.</u>
- P. It is critical to the success of the NRTE comminuted poultry sampling project that sample temperature be properly maintained during collection and shipment. IPP are to avoid storing shipping containers near heaters or in areas exposed to excessive heat. Proper utilization of the packing materials provided for sample collection will help ensure that an appropriate temperature is maintained during shipping.
- Q. IPP are to ship the sample via overnight FedEx courier the same day as they collect the sample or as soon as overnight courier service is available. Samples collected on Friday are to be scheduled, collected, and shipped the same day for arrival at the laboratory on Saturday. IPP are not to ship a sample on Saturday or the day before a Federal holiday.

**NOTE:** Samples that meet discard criteria for only one pathogen may still be tested for the other pathogen (e.g., a sample which is not suitable for *Campylobacter* testing but is suitable for *Salmonella* testing will still be tested for *Salmonella*). Samples and supplies are not to be shared or split with the establishment. However, if the establishment is interested in doing its own analysis, it may use its own supplies to collect a different sample at approximately the same time and point of production the NRTE (raw) comminuted poultry sample is collected.

# VII. USING THE STERILE SCOOP AND SPATULA TO SAMPLE MECHANICALLY SEPARATED CHICKEN OR TURKEY

A. Should IPP need to use the scoop and spatula provided by FSIS to aseptically collect mechanically separated chicken or turkey, they are to designate an area for preparing and gathering sampling supplies. A wheeled cart or table could be used to set up an aseptic area for preparing sampling supplies and for carrying out the actual sample collection procedure. The aseptic area is to be established in a non-contaminated zone as close to the collection site as possible. There can be no compromise in aseptic technique when collecting samples. IPP are to refer to <a href="FSIS Directive 10,250.1">FSIS Directive 10,250.1</a>, Chapter II, Section III.B.5, for instructions on sanitizing work surfaces. In addition to sanitizing work surfaces (including the work

surface of the cart or table), IPP are to sanitize the blades of a clean pair of scissors. IPP are to prepare the Whirl-Pak® bags in a manner that facilitates easy sample collection.

- B. Before putting on the sterile gloves, IPP are to use the sanitized scissors to cut open the package containing the sterile scoop and spatula (without touching the scoop and spatula) and dispense the scoop and spatula onto the aseptic area (see Comminuted Poultry Sampling Supplies and Guidance, box 10; accessible through the "IPP Help" button). IPP are to ensure that the sanitized work surface is dry of antiseptic residue prior to dispensing the scoop and spatula onto it. IPP are not to open the bags containing the sterile scoop and spatula until just before sample collection.
- C. IPP are to next don the sterile gloves using the aseptic technique outlined in Directive 10,250.1, Comminuted Poultry Sampling Supplies and Guidance accessible through the "IPP Help" button.

**NOTE**: Sterile gloves must be worn while collecting samples. The only items that should contact the external surface of the sterile glove on the sampling hand are the sample being collected, the sterile sampling scoop, and (if using) the sterile spatula.

- D. IPP are to pick up the scoop using a gloved hand, collect the sample using the scoop, and carefully deposit the mechanically separated product into the Whirl-Pak® bags (see Comminuted Poultry Sampling Supplies and Guidance, box 11a; accessible through the "IPP Help" button). IPP are to make every effort to avoid touching or contacting the scoop with the Whirl-Pak® bags or any non-sterile material or surface. If possible, IPP are also to avoid getting product on the inside of the bag near the opening. IPP may use the sterile spatula to remove product from the scoop into the Whirl-Pak® bag (Comminuted Poultry Sampling Supplies and Guidance, box 11b; accessible through the "IPP Help" button). IPP may place each Whirl-Pak® bag on the work surface while collecting and depositing the sample into it. (The bag has a gusseted bottom so that once IPP add product it will stand upright. The bag may also be propped up in the sampling caddy, ensuring aseptic technique is maintained.) If needed, another IPP may assist to hold open the bag during sample collection. IPP are to continue to use the scoop in this manner until they have collected a sufficient amount of product to fill the two provided Whirl-Pak® bags up to the fill-line indicated on each bag. IPP are not to underfill or overfill the bag. The total weight of the two bags of samples should be approximately two pounds.
- E. Only when necessary, before folding over the tops of the bags, IPP are to use the individually-wrapped disinfectant towelette provided to wipe away and discard any product that may have gotten onto the outside of the Whirl-Pak® bag (see Comminuted Poultry Sampling Supplies and Guidance, box 12; accessible through the "IPP Help" button). IPP are not to touch or otherwise contaminate the interior surfaces of the Whirl-Pak® bags when wiping the exterior of the bag, and they are to avoid wiping closer than within ¼ inch of the bag opening.
- F. IPP are to prepare and submit the sample as instructed above starting at Section VI. D. 2. Following sample collection, IPP are to dispose of spatula and scoop. IPP are to use a new, sealed spatula and scoop for each sample collection event.

#### VIII. RESULTS

A. Salmonella and Campylobacter results for individual samples collected for the comminuted poultry sampling program and the mechanically separated poultry exploratory sampling project will be posted in LIMS-Direct and PHIS. IPP are to ensure that result information is made available to establishments. Individual sample results for comminuted poultry will be assessed according to the new performance standards beginning July 1, 2016. At this time, the performance standards for comminuted chicken and turkey do not apply to MSC or to MST and results for exploratory sampling of these products will not result in regulatory control actions.

B. If an establishment chooses to perform its own sampling and testing of comminuted poultry product, IPP are to review the results of any testing that the establishment has performed that may have an impact on the establishment's hazard analysis, as described in FSIS Directive 5000.2. If FSIS has evidence to suggest that an establishment's food safety system is not adequate to control pathogens of public health concern, then IPP are to verify that the establishment can support that its sampling and testing procedures are adequate to support decisions in its hazard analysis. IPP are to be aware that if establishments choose to analyze their products for *Salmonella* or *Campylobacter*, they are not required to use the same sample analysis procedures as FSIS. However, IPP are also to be aware that the regulations require the establishment to maintain documents that support its verification activities (including sampling and analysis) and frequency, as appropriate for their intended purpose (9 CFR 417.5(a)(3)). FSIS Directive 5000.2 provides additional instructions regarding review of establishment testing data.

#### IX. DATA ANALYSIS

The Office of Data Integration and Food Protection (ODIFP) will analyze the data collected from the NRTE comminuted poultry sampling program to determine if an establishment is meeting the new performance standards for NRTE (raw) comminuted poultry products. FSIS will use analysis results for MSC and MST to guide policies related to microbial profiles of these products.

#### X. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Staff through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **Notice 36-16** 

Question Field: Enter question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Sampling - Salmonella** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press Continue and at the next screen press Finish Submitting Question.

NOTE: Refer to FSIS Directive 5620.1, *Using* askFSIS or additional information on submitting questions.

Assistant Administrator

Office of Policy and Program Development